Application No.: 10/657,550 Amendment Dated August 13, 2009

Reply to Office Action of April 13, 2009

Amendments to the Claims:

- (Currently Amended) A formulation for the treatment of fungus-induced rhinosinusitis in a mammal, said formulation comprising an aqueous suspension comprising:
- (a) 0.04% to 0.06% by weight of suspended solid steroidal anti-inflammatory particles, wherein the steroidal anti-inflammatory is fluticasone or a pharmaceutically acceptable salt, ester, enol ether, enol ester, acid, or base thereof, said suspended solid steroidal antiinflammatory having the following particle size distribution profile:
- about 10% of the steroidal anti-inflammatory particles have a particle size of less than 0.4 0.90 microns;
- ii. about 25% of the steroidal anti-inflammatory particles have a particle size of less than 0.8 ± 6 microns;
- about 50% of the steroidal anti-inflammatory particles have a particle size of less than 1.5 3-2 microns;
- iv. about 75% of the steroidal anti-inflammatory particles have a particle size of less than 3.0 6.2 microns; and
- about 90% of the steroidal anti-inflammatory particles have a particle size of less than 5.3 10.0 microns; and
- (b) about 0.5 to about 150 mg of an antifungal agent; wherein said formulation is suitable for administration to the nasal-paranasal mucosa.
 - (Cancelled)
 - (Cancelled)
- 4. (Original) The formulation of claim 3, wherein the antifungal agent is amphoteric in $\beta.\,$
- (Original) The formulation of claim 3, wherein said formulation comprises about 7.5 to about 15 mg of amphotericin β.

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 (Original) The formulation of claim 3, wherein said formulation comprises about 10 mg of amphotericin β.

7-9. (Cancelled)

- (Currently Amended) The formulation of claim 1, comprising about 25 50 mcg of said steroidal anti-inflammatory.
- (Original) The formulation of claim 1, comprising about 75 to about 300 mcg of said steroidal anti-inflammatory.
- (Original) The formulation of claim 1, comprising about 200 mcg of said steroidal anti-inflammatory.
- 13. (Previously Presented) The formulation of claim 10, wherein the suspended solid steroidal anti-inflammatory particles have the following particle size distribution profile:
 - about 10% or less of the steroidal anti-inflammatory particles have a particle size of less than 0.40 microns;
 - about 25% or less of the steroidal anti-inflammatory particles have a particle size of less than 0.75 microns;
 - about 50% or less of the steroidal anti-inflammatory particles have a particle size of less than 1.50 microns;
 - about 75% or less of the steroidal anti-inflammatory particles have a particle size of less than 3.0 microns; and,
 - about 90% or less of the steroidal anti-inflammatory particles have a particle size of less than 5.2 microns.

14-21. (Cancelled)

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- 22. (Original) The formulation of claim 1, wherein the formulation is sterile.
- (Original) The formulation of claim 1, wherein the formulation further comprises a preservative.
- (Original) The formulation of claim 23, wherein the preservative is benzalkonium chloride.
 - 25. (Original) The formulation of claim 1, wherein the formulation is stable.
 - 26. (Cancelled)
- (Previously Presented) The formulation of claim 1, wherein the formulation is in a metered-dose spray pump bottle.
- 28. (Previously Presented) The formulation of claim 1, further comprising about 0.01% to about 90% by weight on a dried weight basis of one or more of the following compounds:
 - (a) microcrystalline cellulose;
 - (b) carboxymethyl cellulose sodium;
 - (c) dextrose;
 - (d) benzalkonium chloride;
 - (e) polysorbate 80; and
 - (g) phenylethyl alcohol.
 - 29. (Original) The formulation of claim 1, further comprising an antibiotic.

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30. (Previously Presented) The formulation of claim 29, wherein the antibiotic is one or more selected from the group consisting of amikacin, azithromycin, aztreonan, cefazolin, cefepine, cefonicid, cefaperazone, cefotaxime, cefotetan, cefoxitin, ceftazidime, ceftizoxime, ceftriaxone, cefuroxime, cephapirin, ciprofloxacin, clindamycin, doxycycline, erythromycin lactobionate, gentamicin, kanamycin, linezolid, mezlocillin, mupirocin, nafcillin, netilmicin, neomycin, oxacillin, paromomycin, piperacillin, streptomycin, ticarcillin, tobramycin, and vanoomycin.

31-34. (Cancelled)

- 35. (Currently Amended) A formulation for the treatment of fungus-induced rhinosinusitis, said formulation comprising an aqueous suspension comprising:
 - (a) about 7.5 to about 15 mg of amphotericin β.
 - (b) 0.04% to 0.06% by weight of suspended solid steroidal anti-inflammatory fluticasone propionate particles having the following particle size distribution profile:
 - about 10% of the steroidal anti-inflammatory particles have a particle size of less than <u>0.40 0.70</u> microns;
 - about 25% of the steroidal anti-inflammatory particles have a particle size of less than <u>0.80</u> 1.30 microns;
 - about 50% of the steroidal anti-inflammatory particles have a particle size of less than 1.5 2.5 microns;
 - about 75% of the steroidal anti-inflammatory particles have a particle size of less than 3.0 4.0 microns;
 - about 90% of the steroid particles have a particle size of less than
 5.3 6.0 microns; and,
 - vii. greater than 90% or about 100% of the steroidal anti-inflammatory
 particles have a particle size of less than 10 microns.

wherein said formulation is suitable for administration to the nasal-paranasal mucosa.

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36-70. (Cancelled) .

- (Previously Presented) The formulation of claim 1, further comprising at least at least one complexing agent selected from the group consisting of ethylenediaminetertraacetic acid, citric acid, nitrilotriacetic acid, salts thereof, and sodium edetate.
- 72. (Previously Presented) The formulation of claim 71, wherein the at least one complexing is sodium edetate.
- 73. (Previously Presented) The formulation of claim 35, further comprising at least at least one complexing agent selected from the group consisting of ethylenediaminetertraacetic acid, citric acid, nitrilotriacetic acid, salts thereof, and sodium edetate.
- 74. (Previously Presented) The formulation of claim 73, wherein the at least one complexing is sodium edetate.
- 75. (Currently Amended) A formulation for the treatment of fungus-induced rhinosinusitis, said formulation comprising an aqueous suspension comprising:
 - (a) a therapeutic amount of an antiviral agent selected from the group consisting of Acyclovir, Famciclovir, Valacyclovir, edoxudine, ganciclovir, foscarnet, cidofovir (vistide), Vitrasert and Formivirsen
 - (b) about 7.5 to about 15 mg of amphotericin β;
 - (c) about 10 to about 100 mg of doxycycline
 - (d) 0.04% to 0.06% by weight of suspended solid steroidal anti-inflammatory fluticasone propionate particles having the following particle size distribution profile:
 - about 10% of the steroidal anti-inflammatory particles have a particle size of less than 0.70 microns;

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- about 25% of the steroidal anti-inflammatory particles have a particle size of less than 1.30 microns;
- iv. about 50% of the steroidal anti-inflammatory particles have a particle size of less than 2-5 microns:
- about 75% of the steroidal anti-inflammatory particles have a particle size of less than 4.0 microns;
- about 90% of the steroid particles have a particle size of less than
 6.0 microns: and.
- vii. greater than 90% or about 100% of the steroidal anti-inflammatory particles have a particle size of less than 10 microns.

wherein said formulation is suitable for administration to the nasal-paranasal mucosa.

 (Previously Presented) The formulation of claim 75, wherein the antiviral agent is edoxudine.